IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	))))	C.A. No. 05-356-KAJ (consolidated)

NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6)
TO BARR PHARMACEUTICALS, INC. AND BARR LABORATORIES

PLEASE TAKE NOTICE that on March 30, 2006 commencing at 9:00 a.m., at the offices of Covington & Burling, 1201 Pennsylvania Avenue, N.W., Washington, D.C. 20004, Plaintiffs Janssen Pharmaceutica N.V., Janssen, L.P. and Synaptech, Inc. (collectively, "Plaintiffs" or "Janssen") will take the deposition upon oral examination of Defendants Barr Pharmaceuticals, Inc. and Barr Laboratories (collectively, "Barr") pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure. This deposition upon oral examination will be conducted before an officer authorized to administer oaths and will be recorded by stenographic and videographic means.

Plaintiffs serve this Notice without waiver of its objections to the deficiencies in Barr's document production and other discovery responses concerning the subject matter of the instant Notice, and reserve the right to continue this deposition as necessary in light of any subsequent document production by Barr.

Plaintiffs will take this deposition upon oral examination through one or more officers, directors, managing agents or other persons designated by Barr pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure as the person(s) knowledgeable to testify on Barr's behalf concerning the topics identified in Schedule A. Barr is requested to provide counsel for Plaintiffs with the identity of the individual(s) who will testify regarding each

topic at least one week in advance of the deposition. The deposition will continue from day to day until completed with such adjournments as to time and place as may be necessary. You are invited to attend and examine the witness(es).

ASHBY & GEDDES

/s/ Lauren E. Maguire

Steven J. Balick (I.D. #2114)
John G. Day (I.D. #2403)
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Dated: February 21, 2006
166723.1

SCHEDULE A

Definitions

1. As used herein, "Barr" shall mean Defendants Barr Pharmaceuticals, Inc. and Barr Laboratories and all of Barr's corporate parents, corporate predecessors and past or present subsidiaries, affiliates, divisions, departments, officers, directors, principals, agents and employees.

2. As used herein, "Barr's ANDA" shall mean Barr's Abbreviated New Drug Application Number 77-605.

3. As used herein, "the Generic Product" shall mean the proposed generic galantamine product that is the subject of Barr's ANDA.

4. As used herein, "the '318 patent" shall mean United States Patent No. 4,663,318.

5. As used herein, "document" shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and shall include any means for retaining information.

6. As used herein, "FDA" shall mean the United States Food and Drug Administration.

7. As used herein, "Paragraph IV notice" refers to Barr's May 13, 2005 letter to Plaintiffs attached hereto as Exhibit 1.

8. "Person" and "persons" mean any natural person and any business, legal, corporate, or governmental entity, association, or organization.

9. "Alzheimer's Disease" means any diagnosis, illness, or ailment described as being of the Alzheimer's type, including without limitation Senile Dementia of the Alzheimer's Type, and/or Alzheimer's Dementia.

10. "Galantamine" includes without limitation galantamine, galanthamine, and any salt of galatamine, such as galantamine hydrobromide.

Topics of Examination

1. Barr's Paragraph IV notice including, without limitation, the meaning of, basis for, and any evaluation or analysis concerning the statement set forth in the letter that "Claims 1, 4 and 5 are obvious over Rathmann and Cozantis."

2. The names and responsibilities of all persons who were involved in any evaluation, consideration or discussion to develop the Generic Product conducted by or on behalf of Barr.

3. The decision to file an application with the FDA seeking approval to manufacture and sell a drug product containing galantamine.

4. The names and responsibilities of all persons who were involved in any evaluation, consideration or discussion to license or market the Generic Product conducted by or on behalf of Barr.

5. The benefits, including revenues and profits, that Barr projects, anticipates, expects, or forecasts it will obtain should Barr's ANDA receive approval from the U.S. Food and Drug Administration.

6. Marketing strategies, marketing plans, and projected sales for Barr's Generic Product.

7. Each and every contribution and/or input that Barr, or any employee or agent of Barr, has made to the preparation, decision to file, filing and/or prosecution of Barr's ANDA, including: (a) any information relating to regulatory procedures and strategies for obtaining regulatory approval of the Generic Product of Barr's ANDA; (b) any information comprising, relating to or contained in the 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certifications submitted in connection with Barr's ANDA; and (c) any information comprising, relating to

or contained in the statements of factual and legal basis for invalidity, unenforceability, and/or noninfringement included with the notice of these certifications.

8. The factual basis for Barr's proposed assertion that Barr's ANDA is indicated for the treatment of mild to moderate Alzheimer's disease.

9. The circumstances in which Barr first became aware of galantamine as a treatment for Alzheimer's disease, including but not limited to the date on which this occurred and the people involved.

10. The circumstances in which Barr first became aware of the '318 patent, including but not limited to the date on which this occurred and the people involved.

11. Any consideration or evaluation by Barr to develop a drug product containing galantamine for the treatment of Alzheimer's Disease.

12. Identification of all individuals, whether employees of Barr or third parties, having a role in the consideration or evaluation by Barr to develop a drug product containing galantamine for the treatment of Alzheimer's disease that is the subject of Topic 11, and a description of those roles.

13. Any effort by Barr to develop any drug product other than the Generic Product set forth in Barr 's ANDA.

14. Identification of all individuals, whether employees of Barr or third parties, having a role in the research, development or testing of such a treatment responsive to Topic 13, and a description of those roles.

15. The factual and legal bases for Barr's Affirmative Defense that all the claims of the '318 patent are invalid under one or more of 35 U.S.C. § 101, 102, 103, and 112.

16. The factual and legal bases for Barr's First Claim for Relief that the claims of the '318 patent are invalid according to its proof elements, including an element-by-element comparison of each asserted claim of the '318 patent to the prior art Barr relies upon and the motivation of one of skill in the art to combine any references under 35 U.S.C. §103, as well as a description of any non-prior art defenses such as lack of enablement, insufficient written description, failure to disclose best mode, or claim indefiniteness under 35 U.S.C. § 112.

17. The identity and location of documents and things concerning the foregoing topics.

18. Barr's document retention policies from 1986 to the present.

19. Persons knowledgeable about the subject matter of the foregoing topics.

166723.1

EXHIBIT 1

Sterne Kessler Goldstein Fox
ATTORNEYS AT LAW

May 13, 2005

~~Certified Mail–Return Receipt~~
Via Federal Express

SYNAPTECH, INC.
c/o LADAS & PARRY
Attn: John Richards
26 West 61st Street
New York, NY 10023

Certified Mail–Return Receipt

JANSSEN PHARMACEUTICA N.V.
c/o JOHNSON & JOHNSON
Attn: Audley A. Ciamporcero, Jr.
One Johnson & Johnson Plaza
New Brunswick, NJ 08933

Certified Mail–Return Receipt

Chief Executive Officer
JANSSEN PHARMACEUTICA N.V.
c/o 1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, NJ 08560-0200

Re: Notification Pursuant to § 505(j)(2)(B)(iv)
of the Federal Food, Drug and Cosmetic Act

Dear Sir:

We represent BARR LABORATORIES, INC. ("BARR") of Pomona, New York. We are writing on behalf of our client to provide notice of the following information to SYNAPTECH, INC. ("SYNAPTECH"), the owner of U.S. Patent No. 4,663,318 ("the '318 patent"), according to the records of the U.S. Patent and Trademark Office ("PTO"), and to JANSSEN PHARMACEUTICA N.V. ("JANSSEN"), the owner of U.S. Patent Nos. 6,099,863 ("the '863 patent") and 6,358,527 ("the '527 patent"), according to the records of the PTO, and approval holder of New Drug Application ("NDA") No. 21-169, according to the records of the U.S. Food and Drug Administration ("FDA"):

Pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95(c)(1), we advise you that the FDA has received an Abbreviated New Drug Application ("ANDA") from BARR containing bioavailability and/or bioequivalence data from studies on the galantamine hydrobromide tablets

(4 mg, 8 mg and 12 mg galantamine hydrobromide) that are the subject of NDA No. 21-169. The ANDA was submitted under 21 U.S.C. §§ 355(j)(1), with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") to obtain approval to engage in the commercial manufacture, use or sale of a galantamine hydrobromide drug product before the expiration of the '318, '863 and '527 patents, which are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

Pursuant to 21 C.F.R. § 314.95(c)(2), we advise you that the ANDA submitted by BARR has been assigned the number 77-605 by the FDA.

Pursuant to 21 C.F.R. § 314.95(c)(3), we advise you that the established name of the drug product that is the subject of BARR's ANDA is Galantamine Hydrobromide Tablets, 4 mg, 8 mg and 12 mg ("BARR's ANDA products").

Pursuant to 21 C.F.R. § 314.95(c)(4), we advise you that the active ingredient in the proposed drug product is galantamine hydrobromide; the strengths of the active ingredients in the proposed drug product are 4 mg, 8 mg and 12 mg galantamine hydrobromide; and the dosage form of the proposed drug product is tablets.

Pursuant to 21 C.F.R. § 314.95(c)(5), we advise you that the patents alleged in the Paragraph IV Certification to be not infringed, invalid and/or unenforceable are the '318, '863 and '527 patents. The '318 patent has a listed expiration date in the Orange Book of December 14, 2008. The '863 patent has a listed expiration date in the Orange Book of June 6, 2017. The '527 patent has a listed expiration date in the Orange Book of June 6, 2017.

BARR alleges, and has certified to the FDA, that in BARR's opinion, and to the best of its knowledge, the '318, '863 and '527 patents are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the drug product described in BARR's ANDA. Pursuant to 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(c)(6), BARR's detailed statement of the factual and legal basis for the certification set forth in BARR's ANDA is attached hereto and is made part hereof.

Pursuant to 21 U.S.C. § 355(j)(5)(C), this notice letter includes an Offer of Confidential Access to Application. As required by § 355(j)(5)(C)(i), BARR offers to provide confidential access to certain information from its ANDA No. 77-605 for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought.

Section 355(j)(5)(C)(i)(III) allows BARR to impose restrictions "as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." That provision also grants BARR the right to redact its ANDA in response to a request for Confidential Access under this offer.

permitted by statute, BARR imposes the following terms and restrictions on its Offer ntial Access:

BARR will permit confidential access to certain information from its proprietary JDA No. 77-605 to attorneys from one outside law firm representing SYNAPTECH and n one outside law firm representing JANSSEN; provided, however, that attorneys from h firm(s) do not engage, formally or informally, in patent prosecution for SYNAPTECH JANSSEN. Such information (hereinafter, "Confidential BARR Information") shall be rked with the legend "CONFIDENTIAL".

The attorneys from the outside law firm(s) representing SYNAPTECH or JANSSEN all not disclose any Confidential BARR Information to any other person or entity, luding SYNAPTECH or JANSSEN officers, directors, in-house counsel, employees, tside scientific consultants, and/or other outside counsel retained by SYNAPTECH or NSSEN, without the prior written consent of BARR's outside counsel WINSTON & RAWN, LLP.

As provided by § 355(j)(5)(C)(i)(III) SYNAPTECH's and JANSSEN's outside law m(s) shall make use of the Confidential BARR Information for the sole and exclusive rpose of determining whether an action referred to in § 355(j)(5)(B)(iii) can be brought d for no other purpose. By way of example only, the Confidential BARR Information all not be used to prepare or prosecute any future or pending patent application by NAPTECH or JANSSEN, or in connection with any filing to or communication with the A relating to BARR's ANDA No. 77-605. SYNAPTECH's and JANSSEN's outside law m(s) agree(s) to take all measures necessary to prevent unauthorized disclosure or use the Confidential BARR Information, and that all Confidential BARR Information shall kept confidential and not disclosed in any manner inconsistent with this Offer of nfidential Access. SYNAPTECH's and JANSSEN's outside law firm(s) agree(s) to be ally responsible for any unauthorized disclosure or use of the Confidential BARR formation.

The Confidential BARR Information disclosed is, and remains, the property of RR. By providing the Confidential BARR Information, BARR does not grant NAPTECH or JANSSEN and/or SYNAPTECH's and JANSSEN's law firm(s) any interest in or ense to the Confidential BARR Information.

SYNAPTECH's and JANSSEN's law firm(s) shall, within thirty-five (35) days from e date that it first receives the Confidential BARR Information, return to BARR's outside unsel WINSTON & STRAWN, LLP, all Confidential BARR Information and any copies ereof. SYNAPTECH's and JANSSEN's law firm(s) shall return to WINSTON & STRAWN, P all Confidential BARR Information before any infringement suit is filed by NAPTECH or JANSSEN, if suit is commenced before this 35-day period expires. In the ent that SYNAPTECH or JANSSEN opts to file suit, none of the information contained in

or obtained from any Confidential BARR Information that BARR provides will be included in any publicly-available complaint or other pleading.

(6) Nothing in this Offer of Confidential Access shall be construed as an admission by BARR regarding the validity, enforceability, and/or infringement of any U.S. Patent. Further, nothing herein shall be construed as an agreement or admission by BARR with respect to the competency, relevance, or materiality of any such Confidential BARR Information, document, or thing. The fact that BARR provides Confidential BARR Information upon request of SYNAPTECH or JANSSEN shall not be construed as an admission by BARR that such Confidential BARR Information is relevant to the disposition of any issue relating to any alleged infringement of the '318, '863 or '527 patents, or to the validity or enforceability of those patents.

(7) In the event that SYNAPTECH's or JANSSEN's outside law firm(s), or any other person associated with SYNAPTECH or JANSSEN, violates any provision of this Agreement, BARR will take legal action available to it.

(8) The attorneys from SYNAPTECH's and JANSSEN's outside law firm(s) will acknowledge in writing their receipt of a copy of these terms and restrictions prior to production of any Confidential BARR Information. Such written acknowledgement shall be provided to BARR's outside counsel WINSTON & STRAWN, LLP.

(9) This Offer of Confidential Access shall be governed by the internal laws of the State of Delaware, without regard to any conflict of laws principles.

Section 355(j)(5)(C)(i)(III) provides that any request for access that SYNAPTECH or JANSSEN makes under this Offer of Confidential Access "shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in [this] offer of confidential access" and that the "restrictions and other terms of [this] offer of confidential access shall be considered terms of an enforceable contract." Thus, to the extent that SYNAPTECH or JANSSEN requests access to Confidential BARR Information, it necessarily accepts the terms and restrictions outlined above. Written notice requesting access under this Offer of Confidential Access should be made to:

Lynn M. Ulrich
WINSTON & STRAWN, LLP
35 West Wacker Drive
Chicago, Illinois 60601-9703
Tel: (312) 558-7544
Fax: (312) 558-5700

By providing this Offer of Confidential Access to Application, BARR maintains the right and ability to bring a Declaratory Judgment action under 28 U.S.C. §§ 2201 *et seq.*, pursuant to 21 U.S.C. § 355(j)(5)(C).

Very truly yours,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert C. Millonig

Enclosure: Appendix—Detailed Factual and Legal Basis for BARR's Paragraph IV Certification

Detailed Factual and Legal Basis for
BARR's ANDA Certification that U.S. Patent No. 4,663,318
is Invalid, Unenforceable, and/or Will Not Be Infringed

I. Introduction

This document is the detailed factual and legal basis for the assertion of BARR LABORATORIES, INC. ("BARR") that in its opinion, and to the best of its knowledge, U.S. Patent No. 4,663,318 ("the '318 patent") is invalid, unenforceable and/or will not be infringed by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in BARR's ANDA. The right to raise additional defenses is specifically reserved.

II. Summary

In BARR'S opinion, and to the best of its knowledge, at least claims 1, 4 and 5 of the '318 patent are invalid under 35 U.S.C. § 103(a). Additionally, in BARR'S opinion, and to the best of its knowledge, at least claims 2, 3 and 5-7 would not be infringed either literally or under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in BARR's ANDA.

III. Factual and Legal Basis for BARR's Certification Regarding the '318 Patent

A. The '318 Patent

The '318 patent issued to Bonnie Davis on May 5, 1987 from U.S. Appl. No. 06/819,141, filed January 15, 1986, which does not claim priority to any U.S. or foreign application. The '318 patent is assigned to SYNAPTECH, INC. ("SYNAPTECH").

The '318 patent issued with 7 claims directed to methods of treating Alzheimer's disease and related dementias by administering galantamine.

The '318 patent contains one independent claim. Claim 1 of the patent recites:

> 1. A method of treating Alzheimer's disease and related dementias which comprises administering to a patient suffering from such a disease a therapeutically effective amount of galanthamine or a pharmaceutically-acceptable acid addition salt thereof.

The '318 patent, col. 3, ll. 6-10.

Claims 2-7 depend directly or indirectly from claim 1, and therefore include all of the limitations of claim 1. Claims 4 and 5 are directed to methods of treatment in which the administration of galantamine is oral, and further specify dosages. Claims 2, 3 and 6 are directed to methods of treatment in which the administration of galantamine is parenteral, and further

specify dosages. Claim 7 is directed to a method of treatment in which the administration of galantamine is intracerebroventricular, and further specifies dosages.

B. Selected Prior Art

The content of the prior art on which obviousness may be based is defined by various subsections of 35 U.S.C. § 102.

1. Rathmann

Rathmann, K.L. and Conner, C.S., "Alzheimer's Disease: Clinical Features, Pathogenesis, and Treatment," *Drug Intell. Clin. Pharm. 18*:684-91 (1984) ("Rathmann") was published no later than September 1984, more than one year prior to January 15, 1986. Thus, Rathmann qualifies as prior art to all claims of the '318 patent under 35 U.S.C. § 102(b).

Rathmann teaches that because the cholinergic system is strongly associated with memory and cognition, the primary emphasis in the treatment of Alzheimer's disease is on enhancing cholinergic function, *e.g.*, by administering acetylcholinesterase inhibitors.

Rathmann describes the use of acetylcholinesterase inhibitors, such as physostigmine, as a treatment of Alzheimer's disease. In particular, Rathmann reports results which show significant transient improvement in moderately severe Alzheimer's patients during and after intravenous infusion of physostigmine. Oral administration of physostigmine also resulted in transient improvement in memory with optimal doses at 2-2.5 mg, six times per day (*i.e.*, 12-15 mg/day).

Rathmann further discloses the limited usefulness of physostigmine due to its very short duration of action.

2. Cozanitis

Cozanitis, D.A., "L'hydrobromide de galanthamine: un substitut du sulfate d'éserine (physostigmine) pour le traitement des effets cérébraux des substances anti-cholinergiques," *Nouv. Presse Méd. 34*:4152 (1978) ("Cozanitis") was published no later than October 7, 1978, more than one year prior to January 15, 1986. Thus, Cozanitis qualifies as prior art to all claims of the '318 patent under 35 U.S.C. § 102(b).

Cozanitis describes a report by others that describes the significance of physostigmine in central and peripheral manifestations produced by a surplus of anticholinergic substances. Cozanitis suggests that galantamine hydrobromide (another anticholinesterase substance) can have certain advantages over physostigmine due to its prolonged action. Cozanitis further discloses that the hydrobromide salt of galantamine is able to cross the blood-brain barrier.

C. Invalidity Under 35 U.S.C. § 103(a)

At least claims 1, 4 and 5 are obvious over Rathmann and Cozanitis.

1. The Level of Ordinary Skill in the Art

The first inquiry in an obviousness determination is ascertaining the level of skill of one of ordinary skill in the art. Because of the seriousness of the potential risks associated with designing pharmaceuticals, and the complexity of the field, one of ordinary skill in the art in the field of pharmaceutical research and development would have a relatively high level of education and skill. In performing the other inquiries of an obviousness determination, the prior art must be viewed from the perspective of such a person.

2. The Scope and Content of the Prior Art

For the second inquiry in an obviousness determination, whether a prior art reference falls within the scope and content of the relevant prior art, a court determines the scope of the prior art by examining the field of the inventor's endeavor and the particular problem with which the inventor was involved at the time the invention was made.

The invention claimed in the '318 patent is a method of treating Alzheimer's disease and related dementias by administering galantamine. Further, the specification states that an object of the invention is to improve the cognitive function of patients with Alzheimer's disease. Thus, the relevant prior art includes, *inter alia*, art relating to treatment with galantamine, treatment of Alzheimer's disease and related dementias, and improving cognitive function of patients with Alzheimer's disease.

Rathmann describes treatment of Alzheimer's disease with acetylcholinesterase inhibitors such as physostigmine and improving cognitive function in physostigmine-treated Alzheimer's patients. Cozanitis describes treatment with galantamine hydrobromide as an alternative to physostigmine. Therefore, both of these references are within the scope and content of the prior art relevant to the '318 patent.

3. The Differences Between the Claims and the Prior Art

The third inquiry in an obviousness determination, ascertaining the differences between the claims at issue and the prior art, requires a consideration of both the claimed invention and the prior art as a whole in light of the construction of the claims at issue.

a. Claim 1

Claim 1 of the '318 patent recites a method of treating Alzheimer's disease and related dementias comprising administering to a patient suffering from such a disease a therapeutically effective amount of galantamine or a pharmaceutically-acceptable acid addition salt thereof.

Rathmann teaches the use of anticholinesterase inhibitors, and physostigmine in particular, in the treatment of Alzheimer's disease. Thus, Rathmann explicitly describes each and every limitation of claim 1 of the '318 patent except naming galantamine as an alternative to physostigmine in the treatment of Alzheimer's disease.

Cozanitis teaches galantamine hydrobromide as an alternative anticholinesterase substance to physostigmine. Thus, Rathmann and Cozanitis combined teach all the limitations of claim 1.

One of ordinary skill in the art would have been motivated to combine Rathmann and Cozanitis and achieve the claimed invention based on (1) the disclosure of Rathmann that physostigmine has limited efficacy in the treatment of Alzheimer's due to its short duration of action, and (2) the disclosure of Cozanitis that galantamine hydrobromide is a longer-acting alternative to physostigmine. Furthermore, only routine optimization would be required for one of ordinary skill in the art to determine a therapeutically effective amount of galantamine. Additionally, one would have had a reasonable expectation of success in using galantamine to treat Alzheimer's, given the established clinical usefulness of physostigmine in the treatment of Alzheimer's, the known ability of galantamine to cross the blood-brain barrier, and the known advantages of galantamine over physostigmine. Therefore, Rathmann and Cozanitis combined render claim 1 *prima facie* obvious.

b. Claim 4

Claim 4 of the '318 patent depends from claim 1 and additionally requires that the administration is oral and in the range of 10-2000 mg/day.

In addition to the teachings described for Rathmann and Cozanitis regarding claim 1, above, Rathmann discloses three reports demonstrating transient improvement in memory with oral physostigmine with optimal doses at 2-2.5 mg, six times daily, *i.e.*, 12-15 mg/day, which are within the dosage range required by claim 4. Thus, Rathmann and Cozanitis combined teach all the limitations of claim 4.

One of ordinary skill in the art would have been motivated to combine Rathmann and Cozanitis and achieve the claimed invention for the same reasons as are given for claim 1. Additionally, one would have had a reasonable expectation of success in using galantamine to treat Alzheimer's for the same reasons as are given for claim 1. Furthermore, even if one of ordinary skill in the art would not assume the efficacy of galantamine administered at the dosage disclosed for physostigmine, only routine optimization would be required to arrive at a therapeutically effective dosage of galantamine within the range required by claim 4. Therefore, Rathmann and Cozanitis combined render claim 4 *prima facie* obvious.

c. Claim 5

Claim 5 of the '318 patent depends from claim 4 and additionally requires that the administration is in the range of 100-600 mg/day.

In addition to the teachings described for Rathmann and Cozanitis regarding claim 4, above, only routine optimization would be required for one of ordinary skill in the art to arrive at a therapeutically effective dosage of galantamine within the range required by claim 5.

One of ordinary skill in the art would have been motivated to combine Rathmann and Cozanitis and achieve the claimed invention for the same reasons as are given for claim 1. Additionally, one would have had a reasonable expectation of success in using galantamine to treat Alzheimer's for the same reasons as are given for claim 1. Therefore, Rathmann and Cozanitis combined render claim 5 *prima facie* obvious.

4. Objective Evidence of Nonobviousness

When performing an obviousness analysis, objective evidence of nonobviousness (also called "secondary considerations") must be considered, if present. None of the available information on REMINYL®, the commercial embodiment of the '318 patent claims, is sufficient to rebut a conclusion that claims 1, 4 and 5 are obvious over Rathmann and Cozanitis.

The sales of REMINYL® do not establish that the method of treatment claimed in the '318 patent legally qualifies as "commercial success." The commercial sales of REMINYL® are low and constitute a minor share of the definable market. Furthermore, sales of REMINYL® have neither shown a significant growth in the market nor replaced sales by other products. Finally, BARR is not aware of any public information about any licensing agreements involving the '318 patent. Accordingly, the sales of REMINYL® do not constitute a commercial success sufficient to rebut the established *prima facie* case of obviousness.

BARR is not aware of any specific facts, including any assertions by SYNAPTECH or JANSSEN, that would lead it to conclude that there are unexpected results associated with any of the claimed methods. It has been suggested that galantamine has a dual mechanism of action whereby it inhibits acetylcholinesterase and allosterically modulates nicotinic acetylcholine receptors, and restoration of nicotinic acetylcholine receptor activity has been proposed as a therapeutic approach for the treatment of Alzheimer's disease. However, physostigmine was known to inhibit acetylcholinesterase and allosterically modulate nicotinic receptors. Therefore, the Alzheimer's disease treatment used in the prior art possessed the same activities as galantamine, and there is no evidence of unexpected results regarding galantamine in the treatment of Alzheimer's disease. Accordingly, the purported invention encompassed by claims 1, 4 or 5 of the '318 patent does not exhibit unexpected or superior properties sufficient to rebut the established *prima facie* case of obviousness.

D. Noninfringement

1. No Direct Infringement of Claims 2-3 and 5-7

a. Claims 2, 3 and 6

i. No Literal Infringement

Claims 2, 3 and 6 require a method of treating wherein galantamine is brought into the body through some way other than the digestive tract. BARR's ANDA products and their use do not include a method of treating wherein the drug is brought into the body through some way other than the digestive tract, but rather are labeled for oral administration (*i.e.*, through the digestive tract). Thus, the use of BARR's ANDA products in accordance with the approved labeling would not meet each and every limitation of any of claims 2, 3 and 6. Therefore, each of claims 2, 3 and 6 of the '318 patent will not be literally infringed by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products in accordance with the approved labeling.

ii. No Infringement Under the Doctrine of Equivalents

Because BARR's ANDA products and their use do not include a method of treating wherein the drug is brought into the body through some way other than the digestive tract, a finding that the use of BARR's ANDA products infringed claim 2, 3 or 6 under the doctrine of equivalents would eliminate the parenteral administration element of these claims in its entirety. Moreover, drug bioavailability and pharmacokinetics vary significantly with respect to the route of administration. Thus, there are substantial differences between oral and parenteral administration. Therefore, each of claims 2, 3 and 6 of the '318 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products in accordance with the approved labeling.

b. Claim 5

i. No Literal Infringement

Claim 5 requires a method of treating wherein the dosage of galantamine is 100-600 mg/day. BARR's ANDA products are not labeled to include a method of treating wherein the dosage is 100-600 mg/day, but rather are labeled for administration at dosages of 8-32 mg/day. Thus, the use of BARR's ANDA products in accordance with the approved labeling does not meet each and every limitation of claim 5. Therefore, claim 5 of the '318 patent will not be literally infringed by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products, in accordance with the approved labeling.

ii. No Infringement Under the Doctrine of Equivalents

Furthermore, considering information regarding efficacy and side effects, the recommended dosage range is 16-24 mg/day. A dose of 32 mg/day appears to be at or near the maximum galantamine dose with tolerable side effects. The claimed dosages of 100-600 mg/day are thus approximately 3-19 times the maximum dose with tolerable side effects. Thus, there are substantial differences between the administration of galantamine at 8-32 mg/day and at 100-600 mg/day. Therefore, claim 5 of the '318 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products in accordance with the approved labeling.

c. Claim 7

i. No Literal Infringement

Claim 7 requires a method of treating wherein galantamine is administered directly into the ventricular system of the brain. BARR's ANDA products are not labeled to include a method of treating wherein a drug is administered directly into the ventricular system of the brain, but rather are labeled for oral administration. Thus, the use of BARR's ANDA products in accordance with the approved labeling does not meet each and every limitation of claim 7. Therefore, claim 7 of the '318 patent will not be literally infringed by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products in accordance with the approved labeling.

ii. No Infringement Under the Doctrine of Equivalents

Because BARR's ANDA products and their use do not include a method of treating wherein the drug is administered directly into the ventricular system of the brain, a finding that the use of BARR's ANDA products infringed claim 7 under the doctrine of equivalents would eliminate the intracerebroventricular administration element of this claim in its entirety. Moreover, drug bioavailability and pharmacokinetics vary significantly with respect to the route of administration. Thus, there are substantial differences between oral and intracerebroventricular administration. Therefore, claim 7 of the '318 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products in accordance with the approved labeling.

2. No Indirect Infringement of Claims 2-3 and 5-7

a. Inducement

A successful claim for inducement of infringement requires, *inter alia*, direct infringement. BARR is not liable for inducing infringement of any of claims 2-3 and 5-7 of the '318 patent by selling any of the ANDA products because, as discussed above, no direct infringement of any of these claims will result from its actions.

Additionally, even assuming there is direct infringement, such infringement would not be actively and knowingly aided and abetted by BARR, nor does BARR have the requisite intent to induce or instruct physicians or patients to infringe any of these claims. Claims 2-3 and 5-7 require parenteral administration of galantamine (claims 2, 3 and 6), administration of 100-600 mg/day of galantamine (claim 5), or intracerebroventricular administration of galantamine (claim 7). BARR does not and will not promote or encourage patients to use, or doctors to prescribe, its ANDA products to patients for parenteral or intracerebroventricular administration or at dosages of 100-600 mg/day, but will simply sell galantamine hydrobromide tablets with prescribing information on the product label. BARR's ANDA products label does not indicate that its products should be given parenterally or intracerebroventricularly, or at dosages of 100-600 mg/day, but rather specifies oral administration of galantamine tablets at dosages of 8-32 mg/day. Thus, BARR's ANDA products will in no way induce patients or physicians to infringe the methods of any of claims 2-3 and 5-7 of the '318 patent.

b. Contributory Infringement

A successful claim for contributory infringement requires, *inter alia*, direct infringement. BARR is not liable for contributory infringement of any of claims 2-3 and 5-7 of the '318 patent by selling any of the ANDA products because, as discussed above, no direct infringement of any of these claims will result from its actions.

Additionally, even assuming, *arguendo*, that there is direct infringement and knowledge that BARR's product is being used as a material element in an infringing product, there would not be contributory infringement because there is a substantial non-infringing use with respect to the '318 patent. Claims 2-3 and 5-7 require a method of treating Alzheimer's disease and related dementias wherein galantamine or a pharmaceutically-acceptable acid addition salt thereof is administered parenterally (claims 2, 3 and 6), intracerebroventricularly (claim 7), or orally at a dosage range of 100-600 mg/day (claim 5). BARR's ANDA products labeling does not indicate that BARR's ANDA products should be so administered, but rather specifies that BARR's ANDA products are only for oral administration at a dosage of 8-32 mg/day. Therefore, there is a substantial non-infringing use of BARR's ANDA products because the specified oral administration at a dosage of 8-32 mg/day does not include administration parenterally, intracerebroventricularly, or orally at a dosage range of 100-600 mg/day.

Detailed Factual and Legal Basis for
BARR's ANDA Certification that U.S. Patent No. 6,099,863
is Invalid, Unenforceable, and/or Will Not Be Infringed

I. Introduction

This document is the detailed factual and legal basis for the assertion of BARR LABORATORIES, INC. ("BARR") that in its opinion, and to the best of its knowledge, U.S. Patent No. 6,099,863 ("the '863 patent") is invalid, unenforceable and/or will not be infringed by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in BARR's ANDA. The right to raise additional defenses is specifically reserved.

II. Summary

In BARR'S opinion, and to the best of its knowledge, each of claims 1-10 would not be infringed either literally or under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in BARR's ANDA.

III. Factual and Legal Basis for BARR's Certification Regarding the '863 Patent

A. The '863 Patent

The '863 patent issued to Paul Marie Victor Gilis and Valentin Florent de Condé on August 8, 2000. The '863 patent issued from U.S. Appl. No. 09/202,187 ("the '187 application"), which entered National Stage in the United States under 35 U.S.C. § 371 on December 9, 1998 from International Appl. No. PCT/EP97/02986, filed June 6, 1997 and published as WO 97/47304. The '187 application claims priority to European Appl. No. 96201676, filed June 14, 1996. The '863 patent is assigned to JANSSEN PHARMACEUTICA N.V.

The '863 patent issued with 10 claims directed to tablet formulations of galantamine hydrobromide and to a process of preparing such tablets.

The '863 patent contains one independent claim. Claim 1 of the patent recites:

> 1. A tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

The '863 patent, col. 8, ll. 30-36.

Each of claims 2-10 depends ultimately from claim 1 and is therefore properly construed to include each of the limitations of claim 1. Each of claims 2-9 specifies an additional tablet ingredient (*e.g.*, claim 3 requires that the carrier further comprise a glidant and a lubricant) and/or elaborates a previously specified ingredient (*e.g.*, claim 4 requires that the glidant of claim 3 be colloidal anhydrous silica and that the lubricant of claim 3 be magnesium stearate). Claim 10 is directed to a method of making the tablet according to claim 3.

B. Noninfringement

1. No Literal Infringement of Claims 1-10

Each of claims 1-10 requires that the tablet include, *inter alia*, a spray-dried mixture of (1) lactose monohydrate and (2) microcrystalline cellulose (3) in a 75:25 ratio. BARR's ANDA products contain neither lactose monohydrate nor microcrystalline cellulose. Thus, BARR's ANDA products do not meet each and every limitation of any of claims 1-10. Therefore, each of claims 1-10 of the '863 patent will not be literally infringed by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products.

2. No Infringement Under the Doctrine of Equivalents of Claims 1-10

Considering the claim language, specification and prosecution history of the '863 patent, claim 1 is properly construed as having at least three elements: (1) a diluent containing (2) a disintegrant, and (3) a second disintegrant, wherein the second disintegrant is different from the first disintegrant and is an insoluble or poorly soluble cross-linked polymer disintegrant. BARR's ANDA products formulation contains one diluent and one disintegrant, but no second disintegrant. Thus, at least one element of claim 1 is not present in BARR's ANDA products. Therefore, claim 1 of the '863 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products. Because each of claims 2-10 contains all of the limitations of claim 1, each of claims 2-10 would not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale or use of BARR's ANDA products.

Detailed Factual and Legal Basis for
BARR's ANDA Certification that U.S. Patent No. 6,358,527
is Invalid, Unenforceable, and/or Will Not Be Infringed

I. Introduction

This document is the detailed factual and legal basis for the assertion of BARR LABORATORIES, INC. ("BARR") that in its opinion, and to the best of its knowledge, U.S. Patent No. 6,358,527 ("the '527 patent") is invalid, unenforceable and/or will not be infringed by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in BARR's ANDA. The right to raise additional defenses is specifically reserved.

II. Summary

In BARR's opinion, and to the best of its knowledge, each of claims 1-6 would not be infringed either literally or under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of the drug product described in BARR's ANDA.

III. Factual and Legal Basis for BARR's Certification Regarding the '527 Patent

A. The '527 Patent

The '527 patent issued to Paul Marie Victor Gilis and Valentin Florent de Condé on March 19, 2002. The '527 patent issued from U.S. Appl. No. 09/585,122, filed June 1, 2000, which was a continuation of U.S. Appl. No. 09/202,187 ("the '187 parent application"; now U.S. Patent No. 6,099,863), which entered National Stage in the United States under 35 U.S.C. § 371 on December 9, 1998 from International Appl. No. PCT/EP97/02986, filed June 6, 1997 and published as WO 97/47304. The '187 parent application claims priority to European Appl. No. 96201676, filed June 14, 1996. The '527 patent is assigned to JANSSEN PHARMACEUTICA N.V.

The '527 patent issued with 6 claims directed to methods of treating dementia, mania or nicotine dependence by administering a tablet formulation of galantamine hydrobromide, and to a galantamine hydrobromide tablet made by a recited process.

The '527 patent contains two independent claims, claims 1 and 6. Claim 1 of the patent recites:

> 1. A method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof comprising administering to the patient a tablet comprising as an active ingredient a therapeutically effective amount of galanthamine hydrobromide (1:1) and a pharmaceutically acceptable carrier, wherein said carrier comprises a spray-dried mixture of lactose

> monohydrate and microcrystalline cellulose (75:25) as a diluent, and an insoluble or poorly soluble cross-linked polymer disintegrant.

The '527 patent, col. 8, ll. 30-39.

Each of claims 2-5 depends ultimately from claim 1 and is therefore properly construed to include each of the limitations of claim 1. Each of claims 2-5 specifies the disorder to be treated.

Claim 6 recites:

> 6. A fast-dissolving galanthamine hydrobromide (1:1) tablet made by (i) dry blending the active ingredient, an insoluble or poorly soluble cross-linked polymer disintegrant and an optional glidant with a diluent comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25); (ii) optionally mixing a lubricant with the mixture obtained in step (i); (iii) compressing the mixture obtained in step (i) or in step (ii) in the dry state into a tablet; and (iv) optionally film-coating the tablet obtained in step (iii).

The '527 patent, col. 8, ll. 47-57.

B. Noninfringement

1. No Literal Infringement of Claims 1-6

a. No Literal Infringement of Claims 1-5

Each of claims 1-5 requires that the tablet to be administered include, *inter alia*, a spray-dried mixture of (1) lactose monohydrate and (2) microcrystalline cellulose (3) in a 75:25 ratio. BARR's ANDA products contain neither lactose monohydrate nor microcrystalline cellulose. Thus, BARR's ANDA products do not meet each and every limitation of any of claims 1-5. Therefore, each of claims 1-5 of the '527 patent will not be literally infringed by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products

b. No Literal Infringement of Claim 6

Claim 6 requires that the tablet to be administered be prepared (in part) by dry blending various components with a spray-dried mixture of (1) lactose monohydrate and (2) microcrystalline cellulose (3) in a 75:25 ratio. Because BARR's ANDA products are not prepared using either lactose monohydrate or microcrystalline cellulose, at least one of the

process limitations of claim 6 is not met by the ANDA products. Thus, BARR's ANDA products do not meet each and every limitation of claim 6 of the '527 patent.

Additionally, even if the process limitations are not considered in determining infringement, claim 6 requires that the tablet to be administered contain, *inter alia*, a spray-dried mixture of (1) lactose monohydrate and (2) microcrystalline cellulose (3) in a 75:25 ratio. There is no reason presented in the '527 patent (including its prosecution history) or otherwise to believe that the tablet of claim 6 does not contain the spray-dried mixture of lactose monohydrate and microcrystalline cellulose in a 75:25 ratio. In other words, there is no reason to believe that the tablet of claim 6 is different from the tablet to be administered in claim 1, which recites a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as part of the carrier.

In fact, the specification and prosecution history make clear that the tablet of claim 6 must contain the spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). BARR's ANDA products contain neither lactose monohydrate nor microcrystalline cellulose. Thus, BARR's ANDA products do not meet each and every limitation of claim 6.

Therefore, irrespective of whether or not the process limitations in claim 6 are considered in determining infringement, claim 6 of the '527 patent will not be literally infringed by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products.

2. No Infringement Under the Doctrine of Equivalents of Claims 1-6

a. BARR's ANDA Products are Not Equivalent to the Tablet of Claims 1-6

i. Claim 1

Considering the claim language, specification and prosecution history of the '527 patent, the tablet limitation of claim 1 is properly construed as having at least three elements: (1) a diluent containing (2) a disintegrant, and (3) a second disintegrant, wherein the second disintegrant is different from the first disintegrant and is an insoluble or poorly soluble cross-linked polymer disintegrant. BARR's ANDA products formulation contains one diluent and one disintegrant, but no second disintegrant. Thus, at least one element of claim 1 is not present in BARR's ANDA products. Therefore, claim 1 of the '527 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products. Because each of claims 2-5 contains all of the limitations of claim 1, each of claims 2-5 would not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale or use of BARR's ANDA products.

iii. Claim 6

As discussed above, the tablet of claim 6 contains a "diluent" comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25). For the same reasons as presented regarding claim 1, *above*, this "diluent" should be construed to contain at least two elements—(1) a diluent containing (2) a disintegrant—but may be construed to contain only one element, *viz.*, a diluent.

For the same reasons as presented regarding claim 1, *above*, under either a proper construction of the tablet limitation of claim 1 having at least three claim elements or an incorrect construction of the tablet limitation of claim 1 having but two claim elements, claim 1 of the '527 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products.

b. Prosecution History Estoppel

i. The Applicants Surrendered Equivalents of the "Diluent" of Claim 6

During prosecution, in response to a rejection, the Applicants amended the claim that eventually issued as claim 6 to recite a "diluent comprising a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)". Because this was a narrowing amendment made for a substantial reason related to patentability, there is a presumption that prosecution history estoppel operates to limit the range of equivalents of the "diluent" claim term "a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)". Specifically, there is a presumption that no range of equivalents is available for the "diluent" claim term.

ii. The Applicants Cannot Rebut the Presumption of Estoppel

Even assuming that the diluent in BARR's ANDA products ("the ANDA diluent") could be the equivalent of the spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) ("the claim 'diluent'"), the Applicants have the burden of showing that the amendment that narrowed the claim "diluent" of claim 6 did not surrender the ANDA diluent as an alleged equivalent thereof, *i.e.*, showing that (1) the ANDA diluent was not foreseeable as an equivalent of the claim "diluent"; (2) the rationale underlying the narrowing amendment bears no more than a tangential relation to the ANDA diluent; or (3) there is "some other reason" suggesting that the Applicants could not reasonably have been expected to have claimed the ANDA diluent.

First, were the ANDA diluent an equivalent of the claim "diluent", it would have been foreseeable as an equivalent at the time the narrowing amendment was made. Second, the rationale underlying the narrowing amendment bears more than a tangential relation to the ANDA diluent. In fact, the identity of the "diluent" recited in the claim was of central

First, were the ANDA diluent an equivalent of the claim "diluent", it would have been foreseeable as an equivalent at the time the narrowing amendment was made. Second, the rationale underlying the narrowing amendment bears more than a tangential relation to the ANDA diluent. In fact, the identity of the "diluent" recited in the claim was of central importance to the amendment. Finally, there is not "some other reason" suggesting that the Applicants could not reasonably have been expected to have claimed the ANDA diluent. The ANDA diluent is in the prior art.

Thus, the Applicants cannot rebut the presumption that the amendment that narrowed the claim "diluent" of claim 6 did not surrender the ANDA diluent as an alleged equivalent thereof. For at least these reasons, claim 6 of the '527 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products.

iii. The Applicants Surrendered Equivalents of the "Diluent" of Claims 1-5

If an estoppel arises regarding a particular term in a claim, then that estoppel applies to the same term in other claims. As discussed, the "diluent" claim term "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)" is subject to estoppel by virtue of the amendment to claim 6, there is a presumption that no range of equivalents is available for the "diluent" claim term, and the Applicants cannot rebut this presumption to show that the ANDA diluent was not surrendered as an alleged equivalent. The identical term appears in claim 1, and, by incorporation, in claims 2-5. Thus, there are no available equivalents for "spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25)" in any of claims 1-5.

For at least these reasons, each of claims 1-5 of the '527 patent will not be infringed under the doctrine of equivalents by the importation, commercial manufacture, offer to sell, sale and/or use of BARR's ANDA products.

CERTIFICATE OF SERVICE

I hereby certify that on the 21st day of February, 2006, the attached **NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6) TO BARR PHARMACEUTICALS, INC. AND BARR LABORATORIES** was served upon the below-named counsel of record at the address and in the manner indicated:

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